

In re Application of:
Shapiro et al.
Application No.: 09/993,291
Filed: November 13, 2001
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Atty Docket No.: CIT1440-1

Amendment to the Drawings:

The attached sheet of drawings show changes to figures 1, 3, 4, 8, 9, 12, 14, 17 and 18. These replacement sheets replace the original sheets filed with the application. In each of the sheets, the shaded background has been removed.

Attachments: Replacement Sheets 1, 3, 4, 8, 9 and 12-27.

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REMARKS

Claims 30-39 were pending prior to this Response. By the present communication, no claims added, amended or canceled. Accordingly, claims 30-39 are currently pending in this application.

Objections to the Drawings

Applicants respectfully traverse the objection to figures 1, 3, 4, 8, 9, 12, 14, 17 and 18, as submitted on November 13, 2001. Specifically, the Examiner alleges that the shadings in those figures make viewing the underlying information difficult, and the symbols in Figure 13 are not clear. However, in order to minimize the issues and further prosecution, Applicants have amended figures 1, 3, 4, 8, 9, 12, 14, 17 and 18 as suggested by the Examiner.

Accordingly, Applicants request that the objections to the drawings be withdrawn.

Objections to the Specification

Applicants respectfully traverse the objection of paragraphs [0006] and [0054] in the specification for the informalities listed in the Office Action. However, in order to minimize the issues and further prosecution, Applicants have amended paragraphs [0006] and [0054] as suggested by the Examiner, and request that the objections to the specification be withdrawn.

Rejections under 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 30-39 under 35 U.S.C. § 102(e) as allegedly being anticipated by Thalhammer-Reyero et al. (U.S. Patent No. 6,983,227, hereinafter "Thalhammer-Reyero"). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). Applicants respectfully submit that Thalhammer-Reyero does not provide an

enabling disclosure of the invention automated method for simulating a developmental process of an organism. Specifically, the disclosure by Thalhammer-Reyero provides abstract lineage trees in which the links merely represent descent by cell division, and not actual signaling and mechanical connections between cells in a tissue. Applicants submit that one of skill in the art would require further undue experimentation to arrive at the presently claimed invention in view of Thalhammer-Reyero because Thalhammer-Reyero does not teach one of skill in the art to practice computer algebra or developmental modeling, including variable cell positions, lineage tree, and interactions. Accordingly, Thalhammer-Reyero is not available as a prior art reference under 35 U.S.C. §102(e).

The question of what constitutes undue experimentation was considered in *In re Wands*, 858 F.2d 731, 8 USPQ 2d. 1400 (Fed Cir. 1988). The *Wands* Court approved a prior decision of the PTO Board of Appeals (*Ex parte Forman*, 230 USPQ 456, 457 (Bd. Pat. App. & Int. 1986)), which had listed factors to be considered and then applied them to the case before it. The factors to be considered were: the quantity of experimentation necessary; the amount of direction or guidance provided; the presence or absence of working examples; the nature of the invention; the state of the prior art; the relative skill of those in the art; the predictability or unpredictability of the art; and the breadth of the claims.

The Court in *PPG Industries v. Guardian Industries Corp.* emphasized that a key question in satisfying the enablement requirement is the predictability of the art in question. *PPG Industries v. Guardian Industries Corp.*, 75 F.3d 1558, 37 USPQ 2d. 1618, 1623 (Fed. Cir. 1996). The Court explained:

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. *See, e.g., In re Goodman*, 11 F.3d 1046, 1050-52, 29 USPQ 2d. 2010, 2013-15 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212-14, 18 USPQ 2d. 1016, 1026-28 (Fed.

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Cir.), *cert. denied*, 502 U.S. 856 (1991); *In re Vaeck*, 947 F.2d at 496, 20 USPQ 2d. at 1445.

Inventions directed to the experimental sciences of chemistry and biology have long been considered unpredictable. *Burroughs Wellcome Co. v. Barr Laboratories Inc.* (CA FC) 32 USPQ 2d. 1915. Accordingly, “in cases involving unpredictable factors, such as most chemical reactions and physiological activity, [the] scope of enablement varies inversely with degree of unpredictability of factors involved. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

Applying the enablement test promulgated in *Wands*, Applicants submit that the requirements of *Wands* described above have not been met by the Thalhammer-Reyero disclosure to anticipate the claimed automated methods for simulating a developmental process (*In re Wands*, 858 F.2d 731, 8 USPQ 2d. 1400 (Fed Cir. 1988)). With respect to the first factor, *i.e.*, the quantity of experimentation necessary, Applicants submit that Thalhammer-Reyero provides multiple abstract lineage trees in which the links merely represent descent by cell division. Further, Applicants submit that Thalhammer-Reyero is absolutely silent with regard to data pertaining to the actual signaling and mechanical connections between the cells in a tissue. As indicated in paragraph [0062] of the present application, “process parameters received in step 10 include rate constants, connection strengths, thresholds for activation, cooperativity, spatial geometry including cell position, etc.” (see also, paragraphs [0093]-[0102] of the present application). Accordingly, one of skill in the art in view of Thalhammer-Reyero would be faced with performing undue experimentation to arrive at the claimed invention.

With regard to the second and third *Wands* factors, *i.e.*, the amount of direction or guidance and the presence or absence of working examples, Applicants submit that Thalhammer-Reyero provides no guidance for making or using a mathematical dynamical model of developmental biology. As discussed above, Thalhammer-Reyero is absolutely silent with regard to actual signaling and mechanical connections between the cells in a tissue. Finally, there are no working examples showing specific mathematical equations used in developing a model as described by Thalhammer-Reyero. Applicants submit that the totality of the guidance

provided by Thalhammer-Reyero regarding the computer based virtual models is limited to abstract lineage trees in which the links merely represent descent by cell division.

With regard to the fourth and fifth *Wands* factors, *i.e.*, the state of the prior art and the relative skill of those in the art, it is submitted that art of bioinformatics is extremely complex. Bioinformatics is constantly evolving field in which multiple variables must be considered in creating a developmental model. Accordingly, one of skill in the art would require a detailed description regarding the various mathematical equations necessary to create the automated method for simulating a developmental process of an organism, as claimed in the present invention.

With respect to the sixth *Wands* factor, *i.e.*, the predictability or unpredictability of the art, it is submitted that the invention is in the field of bioinformatics. It is well established that experimental sciences such as biology and chemistry are highly unpredictable, as indicated in the above-cited authorities.

Finally, with respect to the seventh *Wands* factor, *i.e.*, the breadth of the claims, it is submitted that the scope of the pending claims encompasses receiving initial condition values and process parameters for the developmental process of the organism. Thalhammer-Reyero does not teach the mathematical consideration of the actual signaling and mechanical connections between the cells in a tissue. Accordingly, the scope of Thalhammer-Reyero does not encompass the claimed invention.

Anticipation under 35 U.S.C. §102(e) requires that the reference recite each and every element of the claims in a single document, and that the single document provide an enabling disclosure of the *full scope* of the claimed invention. Since Thalhammer-Reyero fails to enable the methods of the claimed invention, Applicants respectfully submit that the Examiner has failed to establish anticipation under 35 U.S.C. §102 (e) over Thalhammer-Reyero. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

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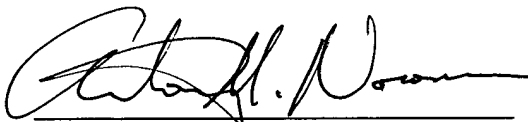
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Conclusion

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

Check number 582631 in the amount of \$510.00 is enclosed as payment for the three-month Extension of Time fee. No other fees are deemed necessary with the filing of this paper. However, The Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,



Date: July 14, 2006

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